

MONSELS SOLUTION- ferric subsulfate paste
Gynex Corporation

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Active Ingredients:

Ferric Subsulfate...20-22% by weight
Other ingredients include thickeners, preservatives and purified water.

Restricted to use by or on the order of a licensed healthcare professional.

Single-Use only. Do not reuse, discard after one use.

Keep cap tightly sealed and away from light.

Store at room temperature (15-30°C).

PRINCIPAL DISPLAY PANEL

REF 5055

8ml

NDC

GYNEX®

MonseI's

Ferric Subsulfate Solution

LOT



5055 BottleLabel REV C 01.20.10

CAUTION: U.S. Federal Law restricts to use by or on the order of a licensed physician.

Active Ingredients

Ferric Subsulfate... 20 – 22% by weight

Other ingredients include thickeners, preservatives, and purified water.

Restricted to use by or on the order of a licensed healthcare professional.

Single-Use only. Do not reuse, discard after one use. Keep cap tightly sealed and away from light. Store at room temperature (15 – 30°C). Made in the U.S.A. Distributed by:

GYNEX – 1 (888) 486-4644

Redmond, WA 98052

MONSELS SOLUTION			
ferric subsulfate paste			
Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:48992-001
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
FERRIC SUBSULFATE (UNII: 3QJ8WS6V8H) (FERRIC CATION - UNII:91O4LML611)		FERRIC CATION	210 mg in 1 g
Inactive Ingredients			
Ingredient Name			Strength

SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
FERRIC SULFATE (UNII: 3HWS7HF5XD)				
SODIUM BENZOATE (UNII: OJ245FE5EU)				
WATER (UNII: 059QF0KO0R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:48992-001-01	14 g in 1 VIAL, SINGLE-DOSE; Type 0: Not a Combination Product	03/13/2020	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other			03/13/2020	

Labeler - Gynex Corporation (012997685)

Establishment			
Name	Address	ID/FEI	Business Operations
Diversified Chemical Products, Inc.		030317424	manufacture(48992-001)